UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,014	12/12/2003	Audrey Goddard	10466/486	2599
C. Noel Kamar	. 7590 05/24/2007 C. Noel Kaman		EXAMINER	
BRINKS HOFER GILSON & LIONE			CHANDRA, GYAN	
P.O. BOX 1039 CHICAGO, IL	•		ART UNIT	PAPER NUMBER
			1646	
			MAIL DATE	DELIVERY MODE
			05/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)
10/735,014	GODDARD ET AL.
Examiner	Art Unit
Gyan Chandra	1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE MAILING BATE of this communication appears on the cover shock with the contrapendence and the
THE REPLY FILED 09 April 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.
1. The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
a) The period for reply expiresmonths from the mailing date of the final rejection.
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL
2. The Notice of Appeal was filed on A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).
AMENDMENTS
3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will <u>not</u> be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below); (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for
appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: (See 37 CFR 1.116 and 41.33(a)).
4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. Applicant's reply has overcome the following rejection(s):
6. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the
non-allowable claim(s).
7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows: Claim(s) allowed:
Claim(s) objected to:
Claim(s) rejected: 22-26.
Claim(s) withdrawn from consideration:
AFFIDAVIT OR OTHER EVIDENCE
8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will <u>not</u> be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome <u>all</u> rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER
11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s).
13. ☐ Other:
\sim \sim \sim
GAMP B. NICKOL, PH.D.
CLIDEDVICORY PATENT FXAMINER

U.S. Patent and Trademark Office PTOL-303 (Rev. 08-06)

TECHNOLOGY CENTER 1600

Application No.

Continuation Sheet (PTO-303)

Continuation of 11 does not place the application in condition for allowance because:

Claim Rejections - 35 USC § 101 and 35 USC § 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 22-26 under 35 U.S.C. § 101 is maintained for the reasons of record as set forth in the office action mailed on 6/13/2006.

The rejection of claims 22-26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the office action mailed on 6/13/2006.

The instant claims are drawn to an isolated antibody that binds to the polypeptide of SEQ ID NO: 83 and that the antibody is a monoclonal or humanized antibody. The claims also recite that the antibody is labeled.

Applicants reiterate their arguments (page 3 of Response) that Example 34 of the instant specification discloses that the PRO361 polypeptide tested positive in the Mixed Lymphocyte Reaction (MLR) Assay. Applicants argue that the MLR assay is art recognized for identifying molecules which suppresses an immune response. Applicants argue (page 5 of Response) that the MLR assay described in the present specification is a comparative assay, meaning that the utility of PRO361 demonstrated by this assay is based upon a comparision of relative expression levels between a known molecule and the unknown PRO361 molecule. Applicants argue that the difference in response between known molecule and unknown molecule in the MLR assay could provide useful information for practical purposes (page 4 of Response). On page 6 of Response, Applicants argue that the instant specification establishes a utility of PRO361 by disclosing that the polypeptide PRO361 is positive in the MLR assay (page 8 of Response). Therefore, the polypeptide is useful as an immunosuppressive agent. Applicants argue that the Fong declaration details the state of the art in the field of immunostimulation/suppression and that there is another application US 10/213,181 which has been allowed on 1/10/2007.

Applicants' arguments have been fully considered but they are not persuasive because the mixed lymphocyte culture (MLC or also known as MLR) is a special case of antigen stimulation in which T lymphocytes respond to foreign histocompatibility antigen on unrelated lymphocytes or monocytes. The office acknowledges that the MLR assay is useful in screening a compound that could have a role in immune response (see previous office action, pg.3). However, Applicants' assertions that the claimed invention could be useful for the treatment of conditions are not persuasive for the reasons of record on page 3-4 of the previous office action of 2/7/2007. There is insufficient data presented to conclude anything regarding the ability of an antibody that binds to the polypeptide PRO361of the invention to be used in a substantial way to therapeutically inhibit an immune response, and much more experimentation would be required to use the invention in this manner. Therefore, one of ordinary skill in the art would not conclude that a molecule which tested positive in the assay (page 141 of the specification) wherein "any decreases below control is considered to be a positive result for an inhibitory compound" would be useful as a molecule in preventing suppression of immune response in an individual (asserted use). In response to Applicants' arguments regarding the Fong's declaration, the Examiner has fully considered but are not persuasive for the reasons of record in pages 4-6 of 11/1/2005 office action. Further, in regarding Applicants' arguments that another application (US 10/213,181) has been allowed are not persuasive because each application is examined on the basis of its own merit. Because Applicants make a note in their Remarks, the Examiner finds that the disclosure of US 10/213,181 and the instant application are not identical. Therefore, the rejection is maintained.